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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

BARBARA SMITH, Plaintiff, v. ETHICON, INC., ETHICON LLC and JOHNSON & JOHNSON, Defendants.	Civil No.: 3:20-cv-00851-MO **DEFENDANTS ETHICON, INC. AND JOHNSON & JOHNSON'S MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.** **Request for Oral Argument**

In accordance with the Court's Pretrial Scheduling Order (Dkt. 307), as amended, Defendants Johnson & Johnson and Ethicon, Inc. (collectively, "Ethicon") submit this supplemental brief in support of their motion to exclude certain general causation opinions of Daniel Elliott, M.D., of which the MDL Court reserved ruling or did not decide. [1]

INTRODUCTION

Plaintiffs designated Elliott (a pelvic surgeon and urologist) to provide general opinions about Ethicon's Prolift device used to treat pelvic organ prolapse, as well as case-specific opinions. *See* Conour Decl., Ex. 1, Elliott Gen. Prolift Rpt.; Conour Decl., Ex. 2, Elliott Case-Specific ("C-S") Rpt.[2] This case was included in Wave 11 of the MDL, and Ethicon challenged many of Elliott's general opinions as part of its challenge in that wave. Although the MDL Court did not rule on Ethicon's Wave 11 challenges, it adopted its Wave 1 rulings in subsequent waves. *See In re: Ethicon, Inc.*, 2016 WL 4500766 (S.D.W. Va. Aug. 26, 2016). The MDL Court held that Elliott is precluded from: (1) opining about the material safety data sheet for polypropylene resin, *In re: Ethicon,* 2016 WL 4500766, at *3; (2) suggesting that alleged degradation causes clinical harm in patients, *id.*; (3) offering legal conclusions, *id.* at *6; (4) speculating about Ethicon's knowledge and state-of-mind and discussing corporate

[1] Pursuant to this Court's July 5, 2022, Order (Dkt. 307), supplemental *Daubert* briefing is to be completed by August 30, 2022. The parties have stipulated to filing opening briefs on August 16, with responsive briefing on August 30, and no replies.

[2] Although Plaintiff Barbara Smith was also implanted with Ethicon's TVT-O device to treat stress urinary incontinence, Dr. Elliott does not believe that she sustained any injuries from that device (*see* Conour Decl., Ex. 2) and Plaintiff has acknowledged that her claims are limited to Prolift.

conduct (including providing marketing opinions, *id*. at *4, 6; and (5) providing a narrative summary of Ethicon's internal documents, *id.* at *6. The MDL Court also limited Elliott's warnings opinions to testimony "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." Conour Decl., Ex. 3, Wave 5 Order at 2.

The parties have stipulated that the MDL Court's prior rulings shall be adopted. Thus, this motion addresses other challenges Ethicon made to Elliott's general opinions that have not been resolved. His opinions on these other issues should be excluded because they are beyond his expertise, irrelevant, unreliable, prejudicial, and/or otherwise improper.

LEGAL STANDARD

Ethicon incorporates by reference the Legal Standard set forth in the contemporaneously filed Supplemental Brief in Support of Motion to Exclude Certain Opinions of Prof. Dr. Med. Uwe Klinge.

ARGUMENT

I. Opinions about non-synthetic mesh procedures as safer alternatives are irrelevant.

A plaintiff may show that a product was defective by pointing to "alternative designs that would have prevented the injury to [plaintiff] without diminishing product safety or utility in other respects." *Purdy v. Deere & Co.*, 386 P.3d 2, 17–18 (Or. Ct. App. 2016). Elliott opines that native tissue repair procedures, such as sacrocolpopexy and colporrhaphy, are a safer alternative to Prolift for the surgical treatment of prolapse. Conour Decl., Ex. 1, Elliott Gen. Rpt. at 67, 57. These alternatives are irrelevant, however, because these alternatives are not alternative designs of Prolift, and in fact, they are not even medical devices. Ethicon challenged these opinions in the MDL as part of the first wave and the

MDL Court determined that "[t]he relevance of this expert testimony is better decided on a case-by-case basis," and, therefore, reserved ruling. *In re: Ethicon*, 2016 WL 4500766, at *4.

Since that time, however, the MDL Court and other courts have excluded similar testimony. For instance, in *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017), the court stated:

> Ethicon argues that Dr. Goodyear's opinions regarding *alternative procedures* are irrelevant to the question of whether a safer alternative *design* of a product exists. Ethicon states, "[A] medical device *product is* not defective in design simply because alternative surgical and nonsurgical *procedures* may exist." Defs.' Mem. Supp. Mot. 4. ***I agree with Ethicon that alternative procedures/ surgeries do not inform the issue of whether an alternative design for a product exists.*** Accordingly, Ethicon's Motion on this point is **GRANTED** and Dr. Goodyear's alternative procedures testimony is **EXCLUDED**.

(Emphasis added.)

Further, in *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 943 (S.D.W. Va. 2017), the MDL Court found that "[e]vidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT [polypropylene mesh device]." The court reasoned that "other surgeries or procedures do not inform the jury on *how* the TVT's design could have feasibly been made safer to eliminate the risks that caused the plaintiffs' injuries." *Id.* (emphasis in original). The court further found that "the plaintiffs must provide evidence of an alternative, feasible design for the *product* at issue," which entails "provid[ing] sufficient evidence to identify a comparable product or design concept, whether the *design features* of the comparable product or the *design concept* existing at the time of the [device's] manufacture . . . ." *Id.* at 944 (emphasis in original).

Many courts, including those within the Ninth Circuit, have adopted the MDL Court's approach. For instance, in *Heinrich v. Ethicon, Inc.*, 2021 WL 2285435, at *2 (D. Nev. June 4, 2021), the court found:

> Dr. Elliott's testimony about other procedures also is not relevant to whether the [pelvic mesh device] is unreasonably dangerous or whether the defendants were negligent because it takes issue with Dr. Hsieh's [the implanter's] choice of treatment. Even if there was some relevance to this evidence, the probative value is substantially outweighed by the danger of unfair prejudice, confusion, and waste of time. Fed. R. Evid. 403. This evidence would result in exploration of whether Dr. Hsieh made the proper medical choice among available alternatives for Heinrich's particular circumstances, instead of whether the defendants' product is unreasonably dangerous for its intended use or the defendants were negligent. *Mullins*, 236 F. Supp. 3d at 943.

See also White v. Ethicon, Inc., 2022 WL 538760, at *3 (W.D. Wash. Feb. 23, 2022) (precluding expert "from testifying that non-synthetic mesh procedures are a safer alternative in support of [plaintiff's] design defect claim."); *Enborg v. Ethicon, Inc.*, 2022 WL 800879, at *4 (E.D. Cal. Mar. 16, 2022) ("Numerous courts have agreed with Ethicon that opinions regarding 'alternative procedures/surgeries' are properly excluded because they 'do not inform the issue of whether an alternative design for a product exists.'") (quoting *In re: Ethicon, Inc.*, 2017 WL 1264620, at *3); *Schmidt v. C.R. Bard, Inc.,* 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) ("[N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to support" a design-defect claim.").[3]

[3] *See also Davis v. Johnson & Johnson*, 2022 WL 2115075, at *4 (D. Kan. June 9, 2022); *Burris v. Ethicon, Inc.*, 2021 WL 3190747, at *8 (N.D. Ohio July 28, 2021); *Hosbrook* v. *Ethicon, Inc.*, 2021 WL 1599199, at *4 (S.D. Ohio Apr. 23, 2021); *Salinero v. Johnson & Johnson*, 2019 WL 7753453, at *17 (S.D. Fla. Sept. 5, 2019); *Wood v. Am. Med. Sys. Inc.*, 2021 WL 1178547, at *5 (D. Colo. Mar. 26, 2021); *Roeder v. Am. Med. Sys, Inc.,* 2021 WL 4819443, at *5 (D. Kan. Oct. 15, 2021); *Lim v. Ethicon, Inc.*, 2021 WL 612399, at *5 (S.D. Miss. Feb. 12, 2021); *Williams v. Ethicon, Inc.*, 2021 WL 857747, at *6 (N.D. Ga. Mar. 8, 2021);

As noted in *Heinrich,* Elliott really takes issues with Plaintiff Barbara Smith's implanting surgeon's choice to recommend one surgery over another. But that choice depends on factors beyond Ethicon's control, including the experience and training of the physician, which is why the law trusts the physician with that decision and does not make the decision for him by allowing a jury to substitute its judgment. *See Willet v. Johnson & Johnson*, 465 F. Supp. 3d 895, 907 (S.D. Iowa 2020) ("The choice of a surgery over a device is a matter of medical judgment of treating doctors, not whether there is a safer alternative design for the product.").

"At bottom, Dr. [Elliott's] proposed alternatives 'are not proposed modifications or improvements of [the product] itself.'" *Enborg*, 2022 WL 800879, at *7 (E.D. Cal. Mar. 16, 2022) (quoting *Meindertsma v. Ethicon, Inc.*, 2021 WL 2010355, at *3 (W.D. Tex. May 17, 2021)). Instead, his opinions would eliminate the device from the market. Under these circumstances and because any potential relevance would confuse the jury and unfairly prejudice Ethicon, the Court should exclude these opinions.

II. Elliott's opinion that a Prolift with a different type of mesh would have been a safer alternative is irrelevant and unreliable.

In his general report, Elliott also vaguely claims that a device with a lighter-weight, larger-pore mesh than the Prolene Soft mesh in Prolift would have been a safer alternative for

Graham v. Ethicon Inc., 2021 WL 5029433, at *4 (N.D. Ga. Aug. 26, 2021); *Labiche v. Johnson & Johnson*, No. CV H-20-4249, 2021 WL 3719554 (S.D. Tex. Aug. 19, 2021); *Pizzitola v. Ethicon, Inc.*, No. 4:20-CV-2256, 2020 WL 6365545, at *4 (S.D. Tex. Aug. 31, 2020); *Robinson v. Ethicon, Inc.*, No. H-20-CV-3760, 2021 WL 5054648, at *45 (S.D. Tex. Nov. 1, 2021).

the treatment of prolapse. Conour Decl., Ex. 1, Elliott Gen. Rpt. at 78, 57.[4] The MDL Court reserved ruling on whether this opinion is reliable, stating that "the lynchpin of Dr. Elliott's testimony is his experience" and that "I am without information sufficient to assess whether this is a reliable foundation." *In re: Ethicon,* 2016 WL 4500766, at *4. This Court should follow other courts that have subsequently found Elliott's opinion unreliable.

The MDL Court has already found that Elliott's opinions are not adequately supported by any testing or the medical literature. *Id.* As noted by the MDL Court, "[i]f the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *In re Ethicon,* 2016 WL 4500766, at *4 (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendment); *see also Siring v. Oregon State Bd. of Higher Educ.*, 927 F. Supp. 2d 1069, 1074 (D. Or. 2013) (same). Elliott does not do so.

In *Heinrich*, *supra*, the court found that the plaintiff did not identify any personal experience of Elliott that supported similar opinions that a lighter-weight/larger-pore mesh would have been safer than Ethicon's TVT-S device to treat stress urinary incontinence. 2021 WL 2285435, at *3-4. The court noted:

> Although Judge Goodwin identified Dr. Elliott's experience as the lynchpin to his testimony's admissibility on this issue, Heinrich ***has not pointed to any evidence of Dr. Elliott's***

[4] Ethicon launched a device known as Prolift+M that contained a lighter-weight mesh known as Ultrapro—the only device that was ever on the market to treat prolapse that had a mesh lighter than Prolene Soft—but Elliott does not identify that as a safer alternative, and in fact, has disavowed it. *See, e.g.*, Conour Decl., Ex. 4, Elliott 4/13/19 Dep. 168:10–13; Conour Decl., Ex. 5, Elliott 9/26/15 Dep. 285:15–22.

> ***experience that would bridge the gap*** between the use of meshes with different pore sizes and weight in the treatment of other medical conditions in other parts of the body and the use in treatment of SUI in the vagina.

Id. (emphasis added).

More recently, an Ohio federal court precluded Elliott from offering the exact same opinion he intends to offer in this case about an alternative to Prolift, finding that "he has not shown that a lighter weight and larger pore size synthetic mesh is a safer alternative design supported by testing, medical or scientific literature or methodology." *Hosbrook*, 2022 WL 136740, at *8; *see also Burton v. Ethicon Inc.*, 2021 WL 1725514, at *3 (E.D. Ky. Apr. 30, 2021) (precluding Elliott from offering this opinion because Elliott offered only "general remarks" unsupported by any substance, and "Elliott has not identified any product that meets or approaches the general description he has provided."); *Arevalo v. Coloplast Corp.*, 2020 WL 3958505, at *12 (N.D. Fla. July 07, 2020) (excluding similar opinions from another pelvic surgeon expert because "(1) [the expert] only cited his 'experience and review and medical literature and other materials' as the basis for his opinion, (2) he provided no explanation as to how those sources support his opinion, and (3) he acknowledged that few un-biased, good-quality studies of tape procedures exist.").

Here, as in those cases, Elliott's report cites numerous alleged problems with Prolift but conspicuously missing are principles or methodology demonstrating that the use of a different type of mesh would be safer. In fact, Elliott stated, "***my ultimate opinion is no meshes should be placed transvaginally***." Conour Decl., Ex. 5, 9/26/15 Dep. 241:14-15 (emphasis added).

III. Elliott should not speculate about the duties of a medical device manufacturer.

Elliott criticizes Ethicon for allegedly failing to comply with duties purportedly owed by a medical device manufacturer. He suggests Ethicon did not (1) perform adequate research and testing before launching Prolift, (2) satisfactorily train physicians to use Prolift, and (3) properly collect and respond to adverse event reports. The MDL Court did not directly address these challenges. Elliott is not qualified to offer these opinions and they are unreliable.

A. Research/Testing

Elliott faults Ethicon for allegedly not performing certain testing and conducting studies. For instance, he states:

- Ethicon failed "to conduct a proper pre-launch evaluation of the Prolift, including but not limited to the failure to prepare an original heavily-researched and objectively-executed clinical evaluation and clinical expert report," Conour Decl., Ex. 1, Elliott Rpt. at 13;
- "The Prolift was never adequately studied before or after launch," *id.*;
- "The lack of adequate clinical studies is exemplified by the ultimate withdrawal of the Prolift from the market," *id.*;
- Ethicon should have "conducted long-term controlled studies prior to any marketing of the Prolift System," *id.* at 33; and
- Ethicon undertook "[i]nadequate pre-launch testing and durability studies," *id.* at 53.

Although the MDL Court stated that "I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research," it found that "because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing

before the trial court before or at trial." *In re: Ethicon*, 2016 WL 4500766, at *6. The MDL Court did not address Elliott's qualifications to offer these opinions.

Elliott is not competent to testify about the level of testing that a manufacturer, such as Ethicon, should have performed. There is nothing in his background that would provide him with specialized knowledge about the testing that Ethicon or other medical device manufacturers supposedly should have performed. He has never manufactured or even worked on the design of a medical device, much less had any involvement with FDA clearance of a medical device. Elliott's resume does "not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion." *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000).

Because Elliott has no relevant experience, he is unable to identify a single rule or regulation that would require Ethicon to conduct different testing. Moreover, Elliott does not identify *any* basis or reason for these opinions, as he must. Instead, his opinion apparently is based purely on unscientific personal belief. When asked about how certain studies/testing should be conducted, Elliott responded that he did not know. *See, e.g.*, Conour Decl., Ex. 5, 9/26/2015 Dep. 259:17-21 ("The basic unfortunate reality is it – I don't know if it could be done.").

Further, Elliott can only speculate about what any testing would have shown. As reasoned by another court, "imposition of liability for breach of an independent duty to conduct long-term testing, where the causal link to the known harm to plaintiff is the ***unknown outcome of testing***

that was not done, would be beyond the pale of any California tort doctrine we can identify." *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1486 (1999) (emphasis in original).

Although the MDL Court did not address Ethicon's challenge to Elliott's qualifications to provide testing opinions, it consistently precluded other surgeons (with similar qualifications – or lack thereof) from testifying about this issue. In its Wave 1 ruling, the Court found "[t]here is no indication that Dr. [Bruce] Rosenzweig has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.,* 2016 WL 4500765, at *5 (S.D.W. Va. Aug. 26, 2016); *see also Huskey v. Ethicon, Inc*., 29 F. Supp. 3d 691, 705 (S.D.W. Va. July 8, 2014) ("there is no indication that [plaintiff's pelvic surgeon expert] has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake"). Further, the MDL Court determined that "[w]hether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct." *Bellew v. Ethicon, Inc*., 2014 WL 12685965, at *9 (S.D.W. Va. Nov. 20, 2014).

Remand courts are in accord. In *Heinrich*, the court found that "Dr. Elliott cannot comment on the defendants' failure to conduct certain testing because he is not qualified to opine on what testing a manufacturer should do, and the 'factual underpinnings' of a lack of testing 'would be nothing more than a summary of corporate documents from an expert witness, which the MDL Court rejected.'" 2021 WL 2285435, at *4; *see also Hosbrook*, 2022 WL 136740, at *7 (precluding Elliott from offering these opinions because he "has no experience as a manufacturer in the research and testing of a medical product" and "[s]uch testimony would be merely a

summary of corporate documents from an expert witness, which the MDL Court rejected"). For these same reasons, Elliott's criticisms about Ethicon's level of testing should be excluded here.

B. Training

Similarly, the Court should preclude Elliott from suggesting that Ethicon failed to properly train physicians to use Prolift. *See* Conour Decl., Ex. 1, Gen. Rpt. at 42-46. The MDL Court did not rule on Ethicon's challenges to this opinion, again noting that it "doubt[s] the relevance of testimony" about "physician outreach," but reserving the issue. *In re: Ethicon*, 2016 WL 4500766, at *6.

Elliott is not qualified to opine about the level of training that a manufacturer is required to provide, and he admitted that he never participated in any Prolift training. Conour Decl., Ex. 6, Elliott 11/15/2012 Dep. 113:3-8; Conour Decl., Ex. 7, Elliott 11/16/2012 Dep. 387:11-21. For the same reasons, the *Heinrich* Court excluded Elliott's training criticisms, finding as follows:

> Heinrich has not pointed to evidence that anyone is going to opine that Dr. Hsieh was inadequately trained or that he improperly implanted the TVT-S. Consequently, whether the defendants failed to train Dr. Hsieh is irrelevant to the issues in this case because there is no evidence that any failure to train led to Heinrich's injuries. Heinrich also has not pointed to evidence that Dr. Elliott is qualified to opine on what training a medical device manufacturer should provide to physicians.

2021 WL 2285435, at *5; *see also Hosbrook*, 2022 WL 136740, at *7 (excluding Elliott's training criticisms because he is unqualified and the plaintiff did not suggest that her implanting surgeon "had inadequate training in the use of the Prolift or incorrectly implanted it"). This Court should reach the same determination.

C. Adverse Event Reports

Elliott also claims Ethicon "fail[ed] to properly evaluate and act in response to adverse event reports[.]" Conour Decl., Ex. 1, Elliott Gen. Rpt. at 55. Elliott's experience as a urologist does not qualify him to criticize the manner by which Ethicon evaluated and acted in response to such reports. He has no relevant experience with the FDA or in the medical device industry that would permit him to offer expert testimony regarding the standard of care for collecting and reporting adverse events. *See, e.g.*, *In re Diet Drugs*, MDL No. 1203, 2001 WL 454586, at *16 (E.D. Pa. Feb. 1, 2001) (excluding heart surgeon's opinions regarding adverse event reporting because surgeon had "no experience or expertise in . . . adverse event reporting" and based his opinions on personal belief rather than reliable methodology).

In its Wave 1 ruling, the MDL Court found that "opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED.**" *In re: Ethicon, Inc.*, 2016 WL 4500766, at *5. The Court should apply that ruling here and confirm that all of Elliott's adverse event reporting opinions are excluded, regardless of whether they are specific to compliance with FDA regulations. In *Walker v. Ethicon, Inc.*, 2017 WL 2992301, at *6 (N.D. Ill. June 22, 2017), an Illinois district court prevented another pelvic surgeon from providing similar criticisms of Ethicon's response to adverse event reports, finding he did not have "relevant experience to testify as an expert" as to "the standard of care for adverse event reporting" and that he "cannot serve as a conduit for corporate information by testifying about the extent of Defendants' adverse event reporting." *See also Hosbrook*, 2022 WL 136740, at *7 (precluding Elliott from offering similar adverse

event opinions). For these same reasons, this Court should preclude Elliott from providing similar testimony.

CONCLUSION

For the reasons set forth above, the Court should limit Elliott's opinions consistent with the above.

DATED: August 16, 2022

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CERTIFICATE OF SERVICE

I hereby certify on August 16, 2022, I electronically filed 16th day of August, 2022, I caused to be served the foregoing **DEFENDANTS ETHICON, INC. AND JOHNSON & JOHNSON'S MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.** with the Clerk of the Court using the CM/ECF system, which will send notification of this Supplemental Briefing to the CM/ECF participants registered to receive service in this matter.

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